UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEHIGH VALLEY TECHNOLOGIES, INC., ENDO GLOBAL VENTURES, ENDO VENTURES LIMITED, AND GENERICS BIDCO I, LLC (d/b/a PAR PHARMACEUTICAL and QUALITEST PHARMACEUTICALS), Plaintiffs, v. VIRTUS PHARMACEUTICALS, LLC, VIRTUS PHARMACEUTICALS OPCO II, LLC, VIRTUS PHARMACEUTICALS HOLDINGS, LLC, AND VIVA PHARMACEUTICAL INC. Defendants.	C.A. No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT

Lehigh Valley Technologies, Inc. ("Lehigh"), Endo Global Ventures ("Endo"), Endo Ventures Limited ("EVL"), Generics Bidco I, LLC (d/b/a Par Pharmaceutical and Qualitest Pharmaceuticals) ("Par") (collectively, "Plaintiffs"), for their Complaint herein, allege as follows:

INTRODUCTION

1. Plaintiffs bring this lawsuit under section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)), the Delaware Deceptive Trade Practices Act (6 Del. C. § 2531 *et seq.*), and the common law. Plaintiffs' claims against Virtus Pharmaceuticals, LLC, Virtus Pharmaceuticals OpCo II, LLC, and Virtus Pharmaceuticals Holdings, LLC (collectively, "Virtus") and Viva Pharmaceutical Inc. ("Viva"), (collectively, "Defendants") arise from

Defendants unfairly competing with Plaintiffs by virtue of their packaging, marketing, promotion, distribution, and sale of a Potassium Chloride for Oral Solution, USP, 20 mEq product that is not approved by the U.S. Food and Drug Administration ("FDA") ("unapproved Potassium Chloride Powder").

2. Pharma Research Software Solution, LLC ("Pharma Research") holds New Drug Application ("NDA") (NDA No. 208019) for Potassium Chloride for Oral Solution, USP, 20 mEq ("Par's Potassium Chloride Powder"). Lehigh obtained an exclusive license from Pharma Research to manufacture, market, distribute, and sell Potassium Chloride Powder for Oral Solution, which is approved by the FDA, and Endo Global Ventures is the exclusive licensee of Lehigh, which itself licensed distribution rights to Generics Bidco I, LLC.[1] The FDA granted approval of Par's product on August 19, 2015 for "the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient." (Exhibit 2 at 1.) Hypokalemia is a deficiency of potassium in the blood stream, and it is potentially life-threatening when not treated.

3. Par's Potassium Chloride Powder is the only FDA approved potassium chloride powder product in the United States. Other companies, including Defendants, sell versions of the drug that are not FDA approved without properly characterizing or representing the unapproved status of the products in the marketing and sales of the products to the public. This causes confusion among consumers and results in Defendants obtaining an unfair advantage in

[1] Endo Global Ventures appointed Endo Ventures Limited distribution, supply, and commercialization rights, and Endo Ventures Limited licensed distribution rights to Generics Bidco I, LLC. Generics Bidco I, LLC does business as Qualitest Pharmaceuticals and distributes its Potassium Chloride Powder product under the Qualitest name. After Par Pharmaceutical, Inc.'s parent company was acquired by a subsidiary of Endo Health Solutions, Inc., Generic Bidco I, LLC also began doing business as Par Pharmaceutical.

the marketplace. This lawsuit arises from the sales and marketing of Defendants' product in competition with Par's Potassium Chloride Powder.

4. On information and belief, Viva manufactures Defendants' unapproved Potassium Chloride Powder in Canada, representing to the Republic of Canada that it is a vitamin, mineral, protein, or unconventional dietary specialty product ("dietary supplement"), even though it is sold in the United States as an unapproved prescription drug. On information and belief, Viva sells the unapproved Potassium Chloride Powder to Virtus for importation into the United States or sells it to Virtus in the United States. Defendants import the unapproved Potassium Chloride Powder, intentionally misrepresent it as a dietary supplement, and subsequently distribute the unapproved Potassium Chloride Powder in the United States as a prescription drug, falsely labeling, advertising, and promoting their Potassium Chloride Powder as an approved drug when, in fact, it is an unapproved drug.

5. Defendants mislead consumers and pass off their Potassium Chloride Powder product in the United States as an FDA approved drug product. On information and belief, Virtus advertises itself as a generic drug company that only sells approved FDA drugs, even though the FDA has not approved its Potassium Chloride Powder. For example, Virtus advertises the following literally false statement: "All of the products at Virtus Pharmaceuticals follow strict FDA guidelines and operating procedures." (Exhibits 8 at 2; Exhibit 12 at 1.) Defendants also mislead pharmacists by intentionally making their unapproved product look like an FDA approved drug, while simultaneously preying on the fact that pharmacists and consumers purchasing their products generally do not understand that drug companies like Defendants are selling unapproved drug products. (*See* Exhibit 11 at 1, 3.) Specifically, Defendants designed their packaging to look like an FDA approved drug, and they omit any

statement that the product is not FDA approved. Defendants likewise fail to disclose the fact that their products are unapproved from prescribing doctors and patients.

6. Defendants also pass off their Potassium Chloride Powder product in the United States as a generic version of Par's FDA approved Potassium Chloride Powder product. In particular, Defendants provide misleading or false information to drug databases, such as Medi-Span, resulting in the database treating Par's approved Potassium Chloride Powder and Defendants' unapproved Potassium Chloride Powder as interchangeable. Such a linking misleads drug database users into believing that Defendants' unapproved Potassium Chloride Powder may be used interchangeably with Par's product even though Par's product is FDA approved and Defendants' product is not.

7. Defendants are unlawfully and falsely advertising, promoting, marketing, selling, and distributing the unapproved Potassium Chloride Powder product throughout the United States, including in Delaware, in direct competition with Par's FDA approved Potassium Chloride Powder product.

8. Plaintiffs bring this action to enjoin Defendants' ongoing violations of the Lanham Act, the Delaware Deceptive Trade Practices Act, and the common law; and Plaintiffs seek to stop Defendants from unfairly competing with Par's Potassium Chloride Powder product by virtue of Defendants' false advertising, marketing, promoting, selling, and distributing of their unapproved Potassium Chloride Powder product. Plaintiffs also seek damages resulting from Defendants' unfair and unlawful conduct as set forth in the Prayer for Relief.

THE PARTIES

9. Lehigh Valley Technologies, Inc. is a Pennsylvania corporation with a place of business in Allentown, Pennsylvania.

10. Endo Global Ventures is incorporated under the laws of Bermuda with a place of business at 22 Victoria Street, Hamilton HM 12, Bermuda.

11. Endo Ventures Limited is incorporated under the laws of Ireland with a place of business at Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

12. Generics Bidco I, LLC (d/b/a Par Pharmaceutical and Qualitest Pharmaceuticals) is incorporated under the laws of the state of Delaware with a place of business in Huntsville, Alabama.

13. On information and belief, Virtus Pharmaceuticals, LLC is a Delaware limited liability company with its principal place of business at 6911 Bryan Dairy Road Suite 210, Largo, Florida 33777. Virtus's corporate headquarters in the United States is located at in 2649 Causeway Center Drive, Tampa, Florida 33619.

14. On information and belief, Virtus Pharmaceuticals OpCo II, LLC is a Delaware limited liability company with its principal place of business in Nashville, Tennessee 37217.

15. On information and belief, Virtus Pharmaceuticals Holdings, LLC is a Delaware limited liability company with its principal place of business in Tampa, Florida 33619.

16. On information and belief, Viva Pharmaceutical Inc. is a Canadian corporation with its principal place of business at 13880 Viking Place, British Columbia, Canada V6V 1K8. On information and belief, Viva conducts business in the United States through its entities J&E International Corp. doing business as Viva Biopharm USA, Inc. which is a Washington corporation with its principal place of business in Ferndale, Washington.

JURISDICTION AND VENUE

17. This action arises under 15 U.S.C. § 1125(a), 6 Del. C. § 2531 *et seq.*, and the common law. This Court has subject matter jurisdiction for each of the claims herein:

(a) False or misleading representations of fact and unfair competition violate section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and this Court has original jurisdiction over such claims by virtue of 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338.

(b) Unfair competition and false advertising violate the Delaware Deceptive Trade Practices Act (6 Del. C. § 2531 *et seq.*), and this Court has supplemental jurisdiction over those claims by virtue of 28 U.S.C. § 1367(a).

(c) Unfair competition violates Delaware common law, and this Court has supplemental jurisdiction over those claims by virtue of 28 U.S.C. § 1367(a).

18. This Court has personal jurisdiction over Virtus because Virtus Pharmaceuticals, LLC, Virtus Pharmaceuticals OpCo II, LLC, and Virtus Pharmaceuticals Holdings, LLC are incorporated in Delaware. *See Daimler AG v. Bauman*, 134 S. Ct. 746, 760, 187 L. Ed. 2d 624 (2014).

19. This Court has personal jurisdiction over Viva because, on information and belief, Viva purposefully directed its business activities into this District by, *inter alia*, contracting with Virtus, to manufacture and import a product, the unapproved Potassium Chloride Powder, for sale in the United States, including in this judicial district. Viva knew or should have known of the lack of FDA approval of the unapproved Potassium Chloride Powder, and its packaging, as well as Virtus's widespread false and misleading statements concerning the product; Viva nevertheless put the unapproved Potassium Chloride Powder into the stream of commerce intending that the unapproved Potassium Chloride Powder would reach consumers in this judicial district. On information and belief, Viva benefitted economically from the distribution of the unapproved Potassium Chloride Powder nationwide, including in this judicial district. On information and belief, Viva has made no attempt to limit the states in which the

unapproved Potassium Chloride Powder would be sold.

20. This Court has personal jurisdiction over Viva because, on information and belief, Viva purposefully directed its business activities into this District by, *inter alia*, working in concert with Virtus to falsely and misleadingly list the unapproved Potassium Chloride Powder in online databases that are used by purchasers of Potassium Chloride Powder in this judicial district. Through such conduct, Defendants have purposefully availed themselves of the privileges of conducting business in this District, and, when engaging in such conduct, it was reasonably foreseeable that Defendants would be subjected to this Court's jurisdiction.

21. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)–(c).

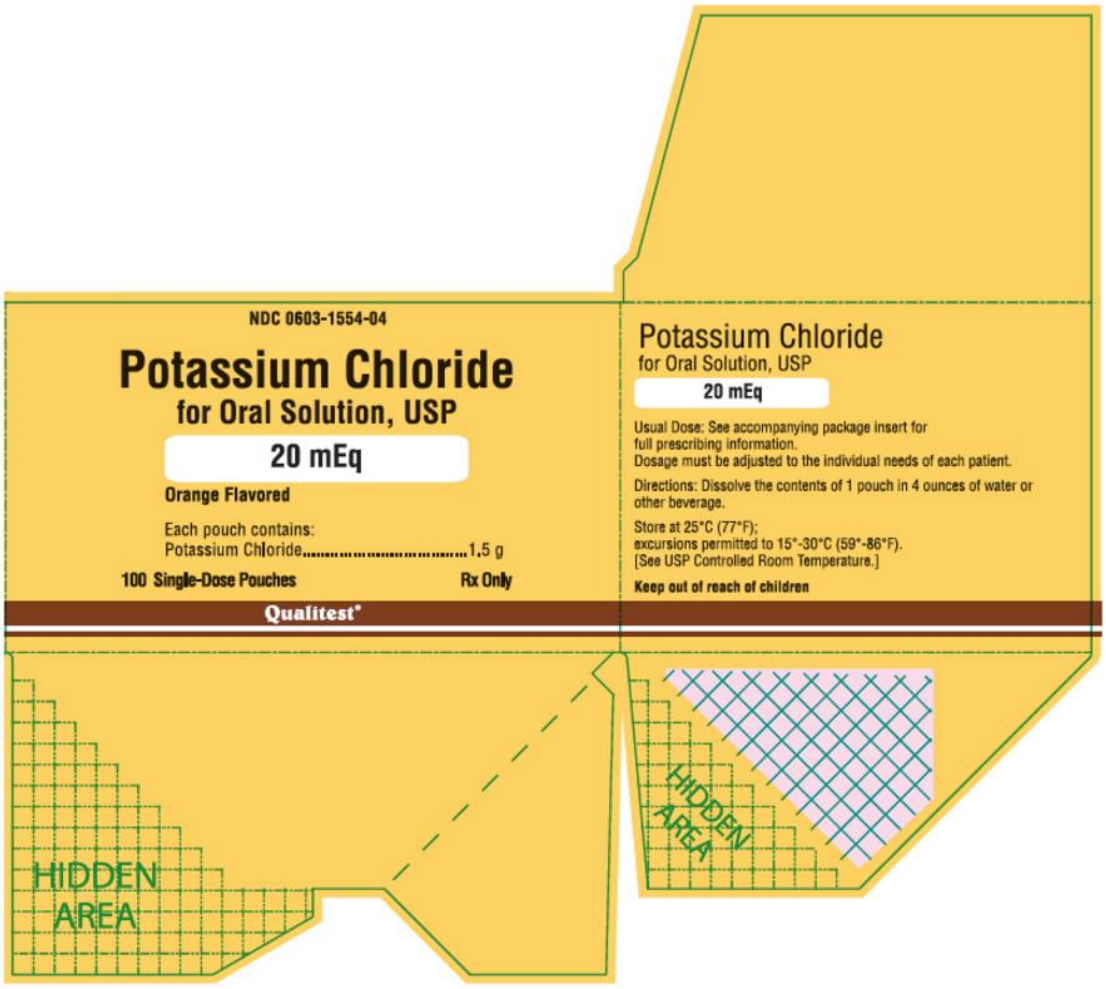
PAR'S FDA APPROVED POTASSIUM CHLORIDE POWDER

22. On October 24, 2014, Pharma Research submitted to the FDA a New Drug Application ("NDA") (NDA No. 208019) for Potassium Chloride for Oral Solution, USP, 20 mEq, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2).

23. In seeking FDA approval of its Potassium Chloride Powder product, Plaintiffs undertook all the necessary steps and incurred the necessary expenses to establish the safety and efficacy of their Potassium Chloride Powder product for purposes of obtaining FDA approval. Plaintiffs gathered, analyzed, and reported relevant clinical data to the FDA and conducted an extensive review of literature, and incurred regulatory, legal, development, and manufacturing costs. Plaintiffs invested a significant amount of time, resources, costs, and effort to establish the safety of their Potassium Chloride Powder product for treatment or prophylaxis of hypokalemia. To date, no other company has invested the time, resources, costs and effort to successfully obtain FDA approval for a Potassium Chloride Powder product.

24. On August 19, 2015, Pharma Research obtained final FDA approval to market and sell its Potassium Chloride Powder product for "the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reductions is insufficient." (Exhibit 2 at 1.) Through a chain of agreements, Generics Bidco I, LLC subsequently obtained distribution rights to the NDA and markets its product under the names of Qualitest Pharmaceutical and Par Pharmaceutical. Par's FDA approved Potassium Chloride Powder product—the only FDA approved Potassium Chloride Powder product—provides physicians and patients with a predictable, safe, and effective drug for the treatment or prophylaxis of hypokalemia, in adults and pediatric patients.

25. Par's product is packaged in 30 unit and 100 unit boxes. (Exhibit 1 at 6.) The FDA reviewed and approved the packaging for Par's Potassium Chloride Powder product, including the contents of the outward facing information for Par's approved Potassium Chloride Powder product, which is depicted below:



(Exhibit 1 at 8.)

26. The FDA's approval letter stated any changes to the drug label (including carton and container labels) would "render the product misbranded and an unapproved new drug." (Exhibit 2 at 2.) In other words, as an approved—and therefore FDA regulated—product, no changes can be made to the label without preapproval from the FDA. (*See id*.)

27. Information regarding the FDA's approval of Par's Potassium Chloride Powder product is publicly available via the FDA website. The FDA maintains a list of all FDA approved drugs in an Approved Drug Products List with Therapeutic Equivalence Evaluations (commonly referred to as the "FDA's Orange Book"). As of June 13, 2016, Pharma Research holds the only approved NDA of Potassium Chloride Powder for Oral Solution USP, 20 mEq,

and there are no approved Abbreviated New Drug Applications for Potassium Chloride Powder for Oral Solution USP, 20 mEq.

28. Par has stockpiled its Potassium Chloride Powder product in order to meet anticipated market demand for the product, in addition to dedicating the attendant quality control and manufacturing resources required for the production of inventory, all of which will require additional expenditures. Par has the capability and capacity to meet the entire United States market's needs for Potassium Chloride Powder.

DEFENDANTS FALSELY ADVERTISE AND PROMOTE THEIR UNAPPROVED POTASSIUM CHLORIDE POWDER PRODUCT AS AN FDA APPROVED DRUG TO CONFUSE CONSUMERS

29. On information and belief, after the August 19, 2015 date when Par's product received FDA approval, Defendants intentionally misled and continue to mislead customers as to the FDA status and nature of their Potassium Chloride Powder product, falsely suggesting and implying that it is FDA approved even though it is not.

30. Defendants' Potassium Chloride Powder is not FDA approved pursuant to an NDA, and it is not a generic version of an approved drug pursuant to an Abbreviated New Drug Application. 21 U.S.C. § 355(b), (j).

31. Defendants' Potassium Chloride Powder is also not exempt from FDA approval under the original Federal Food & Drugs Act in June 1906 ("the 1906 Act"), the 1939 Federal Food, Drug, and Cosmetic Act ("the 1938 FDCA"), or the 1962 amendments to the 1938 FDCA. 21 U.S.C. § 1 (1906) (repealed in 1938 by 21 U.S.C. § 329(a)); 21 U.S.C. § 321(p)(1) (1938); Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781–82 (1962).

32. Whereas unapproved prescription drugs—like Defendants' unapproved Potassium Chloride Powder product—are not regulated by the FDA, approved drugs—like Par's

Potassium Chloride Powder—are heavily regulated by the FDA. For approved drugs, the FDA preapproves drug and promotional labels and regulates advertisements. *See* 21 U.S.C. §§ 321(m), 352(n); 21 C.F.R. §§ 202.1(e)(1), (3), (l)(2), 201.100(d)(1)–(3).

33. The FDA approval status of a prescription drug is material to purchasers because approved drugs provide purchasers assurance as to the quality of the product not afforded to unapproved prescription drugs. Because the marketing of unapproved drugs is not FDA regulated, such marketing may present a serious safety issue. (*See* Exhibit 10 at 1; *see also*, Exhibit 6 at 2; Exhibit 7 at 3.) For example, 40 infants died in early 1980s from taking unapproved Vitamin E intravenous injections (E-Ferol). (Exhibit 7 at 11.) Defendants currently market and sell their unapproved Potassium Chloride Powder for use as a prescription drug to treat serious health conditions, and such marketing and selling is conducted outside the scrutiny of the FDA.

34. On information and belief, if pharmacists knew that Defendants' product was unapproved, they would not purchase it, and would not dispense it to patients. Despite pharmacists' preference for FDA approved prescription drugs, pharmacists are easily misled to purchase and dispense Defendants' product because they believe all prescription drugs are FDA approved. For example, a nationwide survey of 500 pharmacists found that 91% thought all products they dispense are FDA approved. (Exhibit 11 at 3.) The FDA also recognizes that healthcare providers are confused by unapproved drugs:

> Many healthcare providers are unaware of the unapproved status of drugs and have continued to unknowingly prescribe them because the drugs' labels do not disclose that they lack FDA approval. In addition, since many unapproved drugs are marketed without brand names and have been available for many years, it is often assumed that these unapproved drugs are generic drugs. This is not correct. Generic drugs have been evaluated and approved by

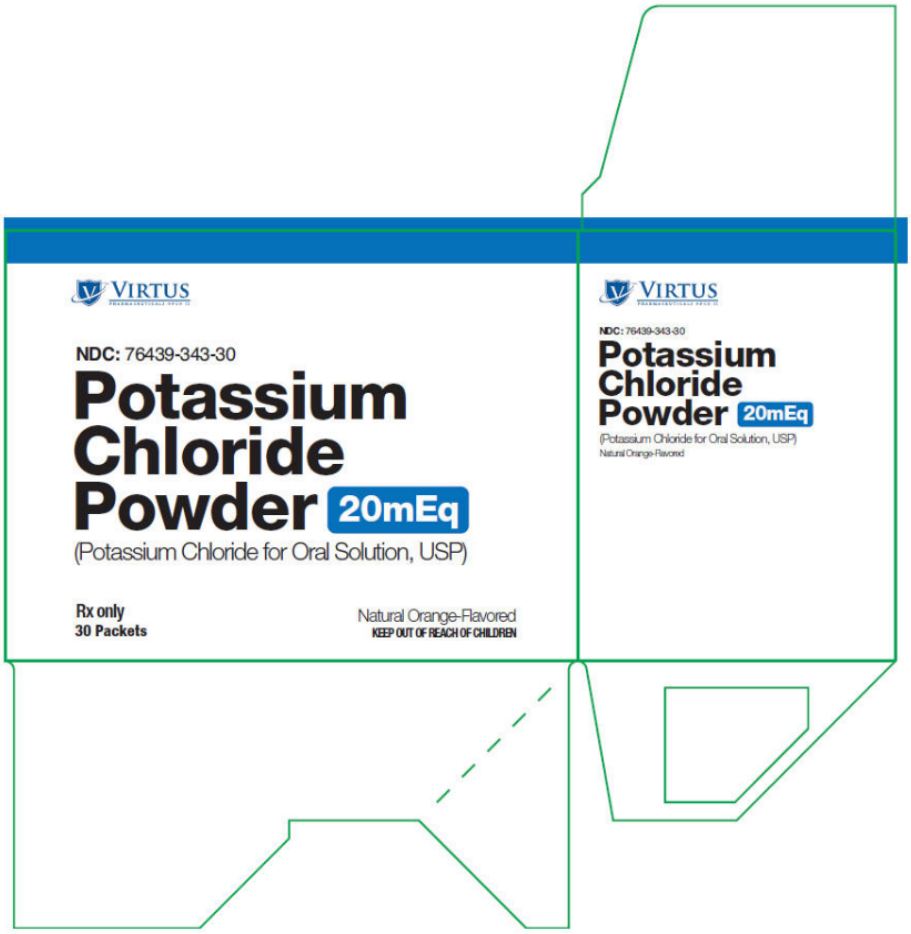
> FDA to demonstrate bioequivalence to a brand name reference drug.

(Exhibit 5 at 1.)

35. Preying upon the misconception of pharmacists, healthcare providers, and the public, Defendants falsely advertise themselves as a generic drug company selling "generic" versions of FDA approved prescription drugs and falsely advertise their Potassium Chloride Powder as an approved drug. Because Defendants' product is cheaper than Par's product, and because customers are misled to believe Defendants' product is FDA approved, customers choose to purchase Defendants' product over Par's product, thereby, directly harming Plantiffs.

Defendants' Product Packaging for Potassium Chloride Powder Is Misleading Because It Omits the Material Fact that It Is Not FDA Approved

36. Defendants intentionally attempt to make their product packaging look like an FDA approved drug. Defendants' product packaging hides the fact that it is an unapproved drug product as depicted below:



(Exhibit 16.)

37. Customers of Defendants' unapproved Potassium Chloride Powder cannot know whether the product is FDA approved or unapproved by looking at the packaging because Defendants omit any disclaimer or notification on the product packaging indicating that the Potassium Chloride Powder is unapproved by the FDA.

38. Defendants' product packaging for the Potassium Chloride Powder product creates the false impression that it is an FDA approved drug because the box indicates that the drug is prescription only, *i.e.*, "Rx only." To further mislead customers, Defendants publicly identify common design themes (*e.g.*, color, font, and placement of information) for their FDA drug products, and then use these themes for their unapproved products to intentionally deceive

and confuse customers. (*See* Exhibit 14 at 1–2.)

39. Defendants further omit any disclaimer on their package insert to inform customers that their unapproved Potassium Chloride Powder is not approved by the FDA. (*See* Exhibit 3.) Instead, Defendants' package insert is designed to resemble a package insert approved by the FDA. For example, it incorporates similar sections and uses similar font and coloring.

40. Because Defendants' product, product label, advertising, and packaging is not FDA approved, their advertising is not pre-approved by the FDA. In contrast, Par's Potassium Chloride Powder product, product label, advertising, and packaging are regulated. This gives Defendants a competitive advantage over Par, especially because customers do not know that Defendants' product is not FDA approved. For example, because Defendants' product is not regulated by the FDA, Defendants may advertise indications and usage of their drug outside any approved indications and usage. Whereas Par's Potassium Chloride Powder product is only indicated "for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose restriction is insufficient," (Exhibit 2 at 1), Defendants' package insert states the following:

> **Indications and Usage**
> 1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis; in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.
> 2. For prevention of potassium depletion when the dietary intake of potassium is inadequate in the following conditions: patients receiving digitalis and diuretics for congestive heart failure; hepatic cirrhosis with ascites; states of aldosterone excess with normal renal function; potassium-losing nephropathy and certain diarrheal states.
> 3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia

> occurs, dietary supplementation with potassium containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

(Exhibit 3.) Pharmacists and customers are misled to believe that Defendants' unapproved Potassium Chloride Powder has more uses than Par's Potassium Chloride Powder, making it more desirable for pharmacists to stock at their pharmacy.

41. On information and belief, Defendants' omission of the material fact that their Potassium Chloride Powder is not FDA approved from their packaging and package insert deceives, or has the capacity to deceive, a substantial segment of customers, including pharmacists.

Defendants' Advertisements Cause Consumers to Falsely Believe that Defendants Only Sell FDA Approved Drugs

42. Virtus states in commerce that it sells "generic" drugs, which affirmatively implies all of Virtus's prescription drug products are FDA approved, including the its unapproved Potassium Chloride Powder. The term "generic" means that the drug is FDA approved based on an Abbreviated New Drug Application. For example, Virtus falsely and publicly states: "All of the products at Virtus Pharmaceuticals follow strict FDA guidelines and operating procedures." (Exhibit 8 at 2; Exhibit 12 at 1.) This statement is false because Virtus's unapproved Potassium Chloride Powder product is not FDA approved.

43. Virtus also advertises itself as a generic drug company on its website with statements like: "OUR VISION: We aspire to make a world of difference in generics," and "OUR PRINCIPLES: In order to be recognized as one of the best service/low cost generic pharmaceutical providers in the industry; to be a leader in introducing new products to our portfolio and to our customers and patients…." (Exhibit 13 at 2–3.) Virtus further touts the virtues of "generic" drugs on its website, and misleads customers by suggesting that all of its

products have met the high standards of the FDA to "ensure that your generic medicine is the same as the brand drug its replaces, and will provide you with the same results." (Exhibit 15 at 3.)

44. A customer attempting to determine whether Virtus's Potassium Chloride Powder product is an authentic, FDA approved drug is falsely misled by reviewing Virtus's public statements about its business and products. Furthermore, although Virtus's website lists certain products, Virtus does not mention its unapproved Potassium Chloride Powder product, thereby promoting further confusion about the nature of its Potassium Chloride Powder product. Virtus's product webpage omits any statement that Virtus offers any prescription drugs that are not FDA approved.

45. On information and belief, because of the public statements that all of Virtus's products comply with FDA guidelines and that its products constitute generic pharmaceuticals, customers of the unapproved Potassium Chloride Powder product reasonably, albeit falsely, believe the product to be FDA approved. On information and belief, Defendants do not want their customers to know before purchasing the Potassium Chloride Powder product that it is not FDA approved. Viva is complicit in Virtus's advertising of Defendants' unapproved Potassium Chloride Powder and knows or should know that Virtus intentionally hides material facts from customers.

Defendants Mislead and Deceive Wholesale Distributors, GPOs, IDNs, and Price Lists as to the Unapproved FDA Status of Their Potassium Chloride Powder

46. Defendants mislead customers by not identifying their product as unapproved to wholesale distributors, who purchase the unapproved Potassium Chloride Power product directly from Virtus. Wholesale distributors include AmeriSourceBergen Corporation, Cardinal Health,

Inc., H.D. Smith Wholesale Drug Company, McKesson Corporation, and Morris & Dickson Company.

47. Because Defendants do nothing to identify their Potassium Chloride Powder as "unapproved" on their product packaging or on their websites. The databases and websites managed by wholesale distributors do not differentiate Par's Potassium Chloride Powder product from the unapproved Potassium Chloride Powder product, causing further deception and confusion.

48. On information and belief, Defendants mislead customers by not identifying their product as "unapproved" to Group Purchasing Organizations ("GPOs") and integrated delivery networks ("IDNs"), which facilitate the purchase of prescription drugs to pharmacies. Such organizations and networks, which include Amerinet, HealthTrust, MedAssets, Novation, and Premier, maintain agreements with manufacturers for purchasing on a national basis various pharmaceutical products used by hospitals and other health care facilities. Hospitals and hospital pharmacies typically participate in such group purchasing programs, and agree to purchase the manufacturers' products under the terms negotiated by the GPO or IDN from wholesalers who are also participants in the GPO or IDN. GPOs and IDNs facilitate the purchase of the unapproved Potassium Chloride Powder product without knowledge that it is not FDA approved.

49. On information and belief, Defendants also mislead customers by not identifying their product as "unapproved" to third-party drug pricing information aggregators ("Price Lists"), who provide pricing information for drugs and pharmaceutical equivalents of those drugs. Price Lists can be integrated with other computerized information systems used by, *e.g.*, GPOs, hospitals, and insurance companies, allowing purchasers to compare drugs and drug prices. Such Price Lists include, for example, Medi-Span and First Databank. On information and belief,

although Defendants provide drug and pricing information for their unapproved Potassium Chloride Powder in Price Lists, Defendants intentionally provide obsolete and incomplete information about their unapproved Potassium Chloride Powder to the Price Lists in order to mislead customers.

50. For example, a customer who searches for potassium chloride oral packet 20 mEq will see Par's FDA approved product along-side Defendants' unapproved Potassium Chloride Powder product, as depicted below:

Search Results for Product Name: **Potassium Chloride Oral Packet 20 MEQ** Include: ☐ Repackaged ☐ Inactives

Records 1 through 12 of 12 << < > >> Page 1

NDC/UPC/HRI	Product Name	Package Size	Package SUM	Package Qty	Package Desc	Labeler Name
00245-0035-89	Klor-Con Oral Packet 20 MEQ	1	EA	1	Packet	SANDOZ
66758-0120-34	Klor-Con Oral Packet 20 MEQ	30	EA	1	Box	SANDOZ
66758-0120-81	Klor-Con Oral Packet 20 MEQ	100	EA	1	Box	SANDOZ
00603-1554-04	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Box	PAR PHARMACEUTICALS
00603-1554-16	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Box	PAR PHARMACEUTICALS
51862-0135-01	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Box	MAYNE PHARMA
51862-0135-02	Potassium Chloride Oral Packet 20 MEQ	1	EA	1	Packet	MAYNE PHARMA
51862-0135-30	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Box	MAYNE PHARMA
64950-0321-01	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Packet	LEHIGH VALLEY TECHNOLOGIES
64950-0321-30	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Packet	LEHIGH VALLEY TECHNOLOGIES
76439-0343-10	Potassium Chloride Oral Packet 20 MEQ	100	EA	1	Box	VIRTUS PHARMACEUTICALS OPCO
76439-0343-30	Potassium Chloride Oral Packet 20 MEQ	30	EA	1	Box	VIRTUS PHARMACEUTICALS OPCO

(Exhibit 4.) The Price List search results do not differentiate Defendants' product as not FDA approved, and as a result, consumers are misled and falsely believe Par and Defendants' products are interchangeable, equivalent, or the same as Par's FDA's approved Potassium Chloride Powder. Even the product information for Par's product identifies Defendants' unapproved product, as depicted below:

NDC/UPC/HRI	Product Name	Package Size	Package SUM	Package Qty	Package Description	Labeler Name	Labeler Code
00603-1554-16	Potassium Chloride Oral Packet 20 MEQ		30 EA		1 Box	PAR PHARMACEUTICALS	00603

GPI Cross Reference - Potassium Chloride Powder Packet 20 mEq (79-70-00-30-00-30-15) - Package Size 30

NDC/UPC/HRI	Product Name	AWP	DP	WAC	ACA FUL	AAWP	GEAP	AWAC	GEWAC	Labeler	MS	TEE	Rx
00245-0035-30	Klor-Con Oral Packet 20 MEQ	$203.74		$145.53		$190.15		$143.19		SANDOZ	Y	NR	R
00603-1554-16	Potassium Chloride Oral Packet 20 MEQ	$322.19		$227.70		$262.73		$200.34		PAR PHARMACEUTICALS	Y	NR	R
50268-0670-30	Potassium Chloride Oral Packet 20 MEQ	$222.59		$185.49				$301.68		AVPAK	Y	NR	R
51862-0135-30	Potassium Chloride Oral Packet 20 MEQ	$185.40		$139.05		$262.73		$200.34		MAYNE PHARMA	Y	NR	R
54868-0356-03	Potassium Chloride Oral Packet 20 MEQ	$107.49				$262.73		$200.34		PHYSICIANS TOTAL CARE	Y	NR	R
64950-0321-30	Potassium Chloride Oral Packet 20 MEQ	$362.02		$301.68				$301.68		LEHIGH VALLEY TECHNOLOGIES	Y	NR	R
66758-0120-34	Klor-Con Oral Packet 20 MEQ	$362.01		$289.60		$262.73		$200.34		SANDOZ	Y	NR	R
76439-0343-30	Potassium Chloride Oral Packet 20 MEQ	$181.32		$145.00		$262.73		$200.34		VIRTUS PHARMACEUTICALS OPCO	Y	NR	R

Ingredients (Set ID: 79763)

Ingredient Name	Strength	Units	Active	Generic ID
POTASSIUM CHLORIDE	20.0000	MEQ	Y	C007447407
FD&C YELLOW #6 (SUNSET YELLOW)	0.0000		N	C002783940

(Exhibit 9 at 5.)

51. On information and belief, Defendants mislead retail pharmacists, hospital pharmacists, and hospital administrators (collectively, "pharmacists") who purchase Defendants' unapproved Potassium Chloride Powder product from wholesale distributors, or through GPOs or IDNs, by hiding the material fact that the product is not FDA approved. Because Defendants do not differentiate their unapproved product and Par's approved product, pharmacists are misled into falsely believing that Defendants' unapproved Potassium Chloride product is in fact FDA approved. Furthermore, physicians writing prescriptions for potassium chloride powder do not know which drug product—*e.g.*, Par's approved product or Defendants' unapproved product—is sold to patients and hospitals when the prescription is filled by pharmacists.

Defendants Import a Dietary Supplement and Pass It Off as a Prescription Drug

52. Defendants intentionally omit the fact that their product is imported as a dietary supplement and not a prescription pharmaceutical product on their product packaging, package insert, and in commercial advertising. Whether a product is a pharmaceutical grade prescription drug as opposed to a dietary supplement is a material fact for customers, including pharmacists, purchasing the product. Virtus represents that this dietary supplement is a prescription drug by labeling its unapproved Potassium Chloride Powder as "Rx," which is literally false.

53. On information and belief, Defendants also mispresent this fact to wholesalers, GPOs, IDNs, and Price Lists. Instead of telling wholesalers, GPOs, IDNs, and Price Lists that their unapproved Potassium Chloride Powder is a dietary supplement, they misrepresent it as a prescription drug. Whether a product is a prescription drug as opposed to a dietary supplement is material for wholesalers, GPOs, IDNs, Price Lists, and other consumers.

Plaintiffs Are Injured by Defendants' False Advertising

54. According to the most recent IMS data, in April 2016 the Defendants' unapproved Potassium Chloride Powder product accounted for approximately 59% of the U.S. market. In contrast, because of Defendants' conduct alleged herein, Par's sales only account for approximately 2% of the U.S. market. Because pharmacists prefer to purchase and dispense FDA approved prescription drugs over unapproved drugs, because Par's Potassium Chloride Powder product is the only FDA approved product in this market, and because Par has the capacity to supply pharmacies with the entire market demand for potassium chloride powder for oral solution, Par would likely fill most or all of Defendants' current market share but for Defendants' false advertising.

55. Defendants' conduct alleged herein has further injured Plaintiffs because Defendants are underselling Par's unapproved product. For example, the current published Wholesale Acquisition Cost ("WAC") for the 30 unit package of unapproved Potassium Chloride Powder product is $145.00, whereas the WAC for Par's product is $227.70. Defendants are able to undersell Plaintiffs' product because of their conduct alleged herein. Because customers falsely believe that Defendants' Potassium Chloride Powder for oral solution is FDA approved, when they see that Defendants' product is cheaper than Par's FDA approved product, they choose the cheaper product.

56. Defendants' conduct has further injured Plaintiffs because it has prevented Plaintiffs' from achieving a fair market price. Because Defendants unfairly compete with Par's product, Plaintiffs are unable to achieve a fair market price for Par's product. Consumers choose Defendants' lower priced, unapproved product because they are misled by Defendants that such products are FDA approved. But for Defendants' conduct, Plaintiffs would be able to achieve a higher market penetration at higher prices due to their position as the only FDA approved Potassium Chloride Powder product on the market. As a result of Plaintiffs' inability to achieve a higher market penetration at higher prices, Plaintiffs cannot recoup their expenditures related to obtaining FDA approval of their Potassium Chloride Powder.

COUNT I:
FALSE ADVERTISING AND UNFAIR COMPETITION
15 U.S.C. § 1125(a)
(AGAINST ALL DEFENDANTS)

57. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–56 of this Complaint.

58. On information and belief, Defendants advertise, promote, distribute, and sell their unapproved Potassium Chloride Powder product throughout the United States and Delaware to wholesale distributors, GPOs, IDNs, hospitals, outpatient centers, pharmacists, physicians, and patients.

59. Defendants advertise, promote, distribute, and sell the unapproved Potassium Chloride Powder product by making false and misleading statements, omissions, and other tactics likely to create false impressions and confusion regarding the FDA approval status of their unapproved Potassium Chloride Powder product. Virtus makes literally false statements such as the following: "All of the products at Virtus Pharmaceuticals follow strict FDA guidelines and operating procedures." (Exhibit 8 at 2; Exhibit 12 at 1.) This statement is

literally false because (i) Virtus sells unapproved drugs in contravention of the requirements of the Food, Drug and Cosmetic Act; (ii) Virtus does not appear on the FDA's Drug Establishments current registration site; and (iii) Virtus has not followed FDA published guidance with respect to seeking FDA approval for unapproved drugs. In addition, in multiple places on its website, Virtus touts the fact that it is a "generic" drug company that specializes in the manufacture and sale of "generic" drugs. It emphasizes that its "generic" drugs are approved by the FDA. These statements, considered in their entirety, are literally false because they convey the necessary implication that all prescription drugs Virtus sells are approved by the FDA.

60. Defendants' product packaging, Virtus's website, and Virtus's intentional omission of the fact that Defendants' product is unapproved from wholesale supplier websites, GPO, IDN, and Price List websites, each deceive a substantial segment of customers. Defendants' false advertising causes buyers to mistakenly conclude that Defendants' unapproved Potassium Chloride Powder product is either interchangeable with Par's FDA approved product or, even worse, that it is safer or more effective than Par's FDA approved product.

61. The FDA approval status of a drug product is material to customers, including pharmacists and end users. Defendants misrepresent the nature, characteristics and qualities of the unapproved Potassium Chloride Powder product through the packaging, commercial advertising, and promotion of this product.

62. As a direct result of the false and misleading descriptions of fact, false and misleading representations, false and deceptive advertising and unfair competition, and other conduct alleged herein, Plaintiffs have suffered, currently suffer, and will continue to suffer damage and irreparable injury, including injury to its business, reputation, and goodwill.

63. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Lanham Act

violations, an accounting for profits on sales of the unapproved Potassium Chloride Powder product, as well as recovery of costs of this action. Furthermore, the conduct alleged herein was undertaken willfully and with the intention of causing confusion, mistake, or deception, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorney fees pursuant to 15 U.S.C. § 1117.

64. Defendants' conduct has caused, and will continue to cause, immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. As such, Plaintiffs are also entitled to injunctive relief as set forth in 15 U.S.C. § 1116.

65. Defendants' conduct, including, *inter alia*, advertising, promotion, selling, and distribution of the unapproved Potassium Chloride Powder product will irreparably harm Plaintiffs and pose grave risks to Delaware purchasers, residents, and other consumers.

COUNT II:
STATUTORY FALSE ADVERTISING
UNDER THE DELAWARE DECEPTIVE TRADE PRACTICES ACT
(AGAINST ALL DEFENDANTS)

66. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–65 of this Complaint.

67. Defendants have made, published, disseminated, and circulated false, deceptive and misleading statements, representations, and advertisements in Delaware, thereby misrepresenting the nature, quality, and characteristics of the unapproved Potassium Chloride Powder product with the intent of selling, distributing, and increasing the consumption of, and interest in, the unapproved Potassium Chloride Powder product.

68. Defendants have engaged in unfair competition and false advertising practices arising under Delaware Deceptive Trade Practices Act, 6 Del. C. § 2531 *et seq.*, § 2532(a)(2) and (a)(12), by and through the false and misleading representations of fact and conduct alleged

herein, *inter alia*, making untrue and misleading statements in advertisements and promotions causing likelihood of confusion or misunderstanding of the FDA approval of the unapproved Potassium Chloride Powder.

69. Defendants acted willfully during the time period relevant to this action, and Defendants unlawfully derived and will continue to derive income profits and goodwill from their wrongful activities. Defendants' conduct has caused, and will continue to cause, immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. As an actual and proximate result of Defendants' willful and intentional actions, Plaintiffs have and will continue to suffer damages, including lost sales, revenue, market share, and asset value in an amount to be determined at trial, and unless Defendants are restrained, Plaintiffs will continue to suffer irreparable harm.

COUNT III:
COMMON LAW UNFAIR COMPETITION
(AGAINST ALL DEFENDANTS)

70. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–69 of this Complaint.

71. Par's Potassium Chloride Powder is the only FDA approved potassium chloride powder product in the United States. Plaintiffs have a reasonable expectation of selling their product in the United States. Other companies, including Defendants, sell versions of the drug that are not FDA approved, and among other things, interfere with Plaintiffs' current and future sales of its product.

72. As a result of Defendants' actions described herein, Plaintiffs have suffered and will continue to suffer substantial damage to their business, reputation, and goodwill; and Defendants' actions constitute a significant threat to Plaintiffs' ability to compete in the

marketplace.

73. Defendants' conduct has caused, and will continue to cause, immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. As a direct and proximate result of Defendants' willful and intentional actions, Plaintiffs have and will continue to suffer damages, including lost sales, revenue, market share, and asset value in an amount to be determined at trial. Plaintiffs suffer irreparable damage, and unless Defendants are restrained, Plaintiffs will continue to suffer irreparable damage.

COUNT IV:
CONTRIBUTORY FALSE ADVERTISING
15 U.S.C. § 1125(a)
(AGAINST VIVA)

74. Plaintiffs reallege and incorporate herein the allegations contained in paragraphs 1–73 of this Complaint.

75. On information and belief, based on the conduct alleged herein, Virtus has engaged in false advertising that has injured Plaintiffs.

76. On information and belief, Viva actively engages in the false advertising, but Viva is alternatively contributorily liable because it induces Virtus's misleading conduct. Viva contributes to Virtus's false advertising because, for example, Viva supplies the unapproved Potassium Chloride Powder product to Virtus, and Viva knows or should know about Virtus's false advertising.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court enter judgment against Virtus and Viva as follows:

A. That Virtus and Viva and all of their respective officers, agents, representatives, employees, attorneys, and all other persons acting in concert with them be permanently enjoined from:

1. listing the unapproved Potassium Chloride Powder product on databases, including but not limited to Medi-Span and First Databank until such time as those databases provide clear and conspicuous notice that Defendants' unapproved Potassium Chloride Powder product is not FDA approved as safe and effective for treating any condition;

2. directly or indirectly engaging in false advertising or promotions of the unapproved Potassium Chloride Powder product or using such advertising or promotions to induce others to substitute the unapproved Potassium Chloride Powder product for Par's FDA approved Potassium Chloride Powder product;

3. making or inducing others to make any false, misleading or deceptive statements of fact, or representations of fact, in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution (including but not limited to repackaging) of the unapproved Potassium Chloride Powder product in such a fashion as to suggest that such product is a generic or equivalent to Par's FDA approved Potassium Chloride Powder product, or can be interchanged with or substituted for prescriptions of Par's FDA approved Potassium Chloride Powder product; and

4. directly or indirectly engaging in false advertising or promotions of the unapproved Potassium Chloride Powder product as FDA approved, including any representation, description, or statement that would imply that its product is interchangeable or an equivalent of any previously approved Potassium Chloride Powder product; which representation, description, or statement may mislead others to believe that the unapproved product is FDA approved;

B. That Virtus and Viva be ordered to correct any erroneous impression persons may have derived concerning the nature, characteristics, or qualities of either the unapproved Potassium Chloride Powder product or Par's FDA approved Potassium Chloride Powder product, including without limitation:

1. sending a registered letter (with a copy to Plaintiffs) to all Price List databases that list the unapproved Potassium Chloride Powder product, including but not limited to Medi-Span and First Databank, requesting that the unapproved Potassium Chloride Powder product be immediately listed as obsolete in said Price List databases, and instructing them to remove any listing of unapproved Potassium Chloride Powder product in said Price List databases or to insert a clear and conspicuous notice that the unapproved Potassium Chloride Powder product is not FDA approved as safe and effective for treating any condition, as soon as commercially possible;

2. placing corrective advertising, for a period of 12 months, in the form of a printed advertisement on their websites stating that the unapproved Potassium Chloride Powder product is not FDA approved in a font no smaller than the font used throughout their websites; and

3. providing notice to each person or entity that purchased, dispensed, ordered, and/or prescribed the unapproved Potassium Chloride Powder (including wholesale generic drug purchasers, pharmacists, GPOs, outpatient centers, hospitals, doctors, and purchasers or buyers of such products) that the FDA has approved only Par's Potassium Chloride Powder product;

4. providing a disclaimer on the Defendants' packaging stating that the product is not FDA approved;

C. That Virtus and Viva be adjudged to have violated the provisions of 15 U.S.C. § 1125(a) by unfairly competing against Plaintiffs by using false or misleading descriptions or

representations of fact that misrepresent the nature, quality, and characteristics of the unapproved Potassium Chloride Powder product;

D. That Virtus and Viva be adjudged to have unlawfully competed against Plaintiffs by engaging in unfair competition and false advertising under Delaware Deceptive Trade Practices Act (6 Del. C. § 2531 *et seq.*);

E. That Virtus and Viva be adjudged to have unlawfully competed against Plaintiffs by engaging in unfair competition under the common law;

F. That Virtus and Viva recall and remove unapproved products from the distribution supply chains until such time as they clearly and conspicuously state that the unapproved Potassium Chloride Powder product is not FDA approved;

G. That Plaintiffs be awarded damages pursuant to 15 U.S.C. § 1117, sufficient to compensate it for the damage caused by the false and misleading statements related to the unapproved Potassium Chloride Powder product;

H. That Plaintiffs be awarded profits derived by reason of said acts, or as determined by an accounting;

I. That such damages and profits be trebled and awarded to Plaintiffs and that they be awarded its costs, attorneys' fees and expenses in this suit under 15 U.S.C. § 1117 and under the Delaware Deceptive Trade Practices Act (6 Del. C. § 2531 *et seq.*), as a result of the willful, intentional and deliberate acts in violation of the Lanham Act and the Delaware Deceptive Trade Practices Act;

J. That Plaintiffs be awarded damages in an amount sufficient to compensate them for the damage caused by Virtus's and Viva's unlawful competition and false or misleading acts

and deceptive trade practices under the Delaware Deceptive Trade Practices Act (6 Del. C. § 2533(b)–(c)) and the common law;

K. That Plaintiffs be granted injunctive relief under the Delaware Deceptive Trade Practices Act (6 Del. C. § 2531 *et seq.*);

L. That all of Virtus's and Viva's misleading materials and products be destroyed as allowed under 15 U.S.C. § 1118;

M. That Virtus and Viva file, within ten days from entry of an injunction, a declaration with this Court signed under penalty of perjury certifying the manner in which Virtus and Viva have complied with the terms of the injunction;

N. That Plaintiffs be granted pre-judgment and post-judgment interest;

O. That Plaintiffs be granted costs associated with the prosecution of this action; and

P. That Plaintiffs be granted such further relief as the Court may deem just.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury of all issues in this case.

Dated: June 13, 2016

By: /s/ Steven L. Caponi

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